

December 19, 2003

Michael O. Leavitt, Administrator
U.S. Environmental Protection Agency
Ariel Rios Building, 1101-A
1200 Pennsylvania Ave., N.W.
Washington, DC 20460

Subject: Comments on the HPV Test Plan for 1,3,4-Thiadiazole,2,5-bis(tert-nonyldithio)

Dear Administrator Leavitt:

The following comments on the test plan for the chemical 1,3,4-Thiadiazole,2,5-bis(tert-nonyldithio) sponsored by the Petroleum Additives Panel HERTG group of the ACC are submitted on behalf of the Physicians Committee for Responsible Medicine, People for the Ethical Treatment of Animals, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These health, animal protection, and environmental organizations have a combined membership of more than ten million Americans.

ACC's HERTG submitted its test plan on August 13, 2003 for 1,3,4-Thiadiazole,2,5-bis(tert-nonyldithio), CAS No. 89347-09-1, which is mostly used as a corrosion inhibitor and extreme pressure agent in finished greases and lubricating oils. This chemical is sold to fuel blenders in its neat form and to finished oil blenders in both the neat form and in additive packages. There is very little data available on physicochemical properties, environmental fate, and human health effects for this chemical. To its credit, HERTG did review a substantial number of online sources and databases for experimental data on SIDS endpoints (see test plan, p. 2); many of these sources are listed in the October 1999 letter to participants in the HPV program (Wayland 1999). A review of these sources by PCRM failed to locate existing studies addressing repeated dose, reproductive, or developmental toxicity for 1,3,4-Thiadiazole,2,5-bis(tert-nonyldithio). In order to meet these SIDS data requirements, HERTG has proposed to conduct a combined repeated dose/reproductive/developmental toxicity study, OECD 422, which will result in the death of at least 675 animals.

However, PCRM was able to identify screening assessment studies being conducted on 1,3,4-Thiadiazole,2,5-bis(tert-nonyldithio) in Canada. We are surprised that HERTG overlooked this information and we strongly urge HERTG to await the results of the Canadian screening assessment studies in order to avoid separate and/or duplicative testing for repeated dose, reproductive, and developmental toxicity endpoints. Duplicative studies violate the basic tenets of animal welfare and the HPV program. In

keeping with animal welfare principles set forth by the EPA, including EPA's stated goal that HPV participants "maximize the use of existing and scientifically adequate data to minimize further testing" (Wayland 1999), the EPA should ask the ACC to wait for the Canadian results before deciding whether to conduct its own repeated dose/reproductive/developmental tests.

The Domestic Substances List (DSL) Categorization and Screening Program, an initiative of the Canadian Environmental Protection Act of 1999 (CEPA 1999), initiated a pilot project which will assess potential risk to humans and/or the environment of 123 substances, including 1,3,4-Thiadiazole,2,5-bis(tert-nonyldithio), please see <http://www.ec.gc.ca/substances/ese/eng/dsl/pilpro.cfm>. CEPA requires Canadian manufacturers or importers to submit information on this chemical, including toxicity and exposure data. We are concerned that collaboration between member states of the Organization for Economic Co-operation and Development (OECD), such as the U.S. and Canada, appears to be limited. This would demonstrate a serious lack of concern for animal welfare since separate and/or duplicative testing results in the death of many additional animals.

We are hopeful that HERTG will reconsider their proposal to kill 675 animals in a combined repeated dose/reproductive/developmental toxicity study which may be completely redundant. We strongly urge the EPA to require that ACC wait for the results of the screening assessment studies for 1,3, 4-Thiadiazole,2,5-bis(tert-nonyldithio) already underway in Canada. Thank you for your attention to these comments. I may be reached at 202-686-2210, ext. 327, or via e-mail at meven@pcrm.org.

Sincerely,

Megha Even, M.S.
Research Analyst

Chad B. Sandusky, Ph.D.
Director of Research

References

Wayland, S.H. Letters to manufacturers/importers, Oct. 4, 1999, <http://www.epa.gov/chemrtk/ceoltr2.htm>.